

Winston & Strawn LLP  
101 California Street  
San Francisco, CA 94111-5802

James F. Hurst (admitted pro hac vice)  
*jhurst@winston.com*

Maureen L. Rurka (admitted pro hac vice)  
*mrurka@winston.com*

James M. Hilmert (admitted pro hac vice)  
*jhilmert@winston.com*

WINSTON & STRAWN LLP  
35 West Wacker Drive  
Chicago, IL 60601-9703  
Telephone: (312) 558-5600  
Facsimile: (312) 558-5700

K. Joon Oh (SBN: 246142)  
*koh@winston.com*

WINSTON & STRAWN LLP  
101 California Street  
San Francisco, CA 94111-5802  
Telephone: (415) 591-1000  
Facsimile: (415) 591-1400

Attorneys for Plaintiff  
SANDOZ INC.

**UNITED STATES DISTRICT COURT**

**NORTHERN DISTRICT**

SANDOZ INC.,

Plaintiff,

v.

AMGEN INC. and HOFFMAN-LA ROCHE  
INC.,

Defendants.

**Case No. 3:13-cv-02904-MMC**

**SUPPLEMENTAL DECLARATION OF  
BRIAN HIRSCH IN SUPPORT OF AMGEN  
INC. AND HOFFMANN-LA ROCHE INC.'S  
MOTION TO FILE UNDER SEAL, D.I. 71**

I, Brian Hirsch, hereby declare as follows:

1. I am the Head, US Patent Litigation, for Sandoz Inc. In this role, I have supervisory responsibility for intellectual property matters relating to, among other things, the Sandoz biologic drug product etanercept described in the Complaint. I am over twenty-one years of age and have either personal knowledge, or institutional knowledge based on my supervisory responsibility, of each of the facts stated in this declaration. If called upon, I could and would testify completely and truthfully about these facts.

2. Defendants Amgen Inc. and Hoffman-La Roche Inc. have filed an administrative motion to file under seal specific portions of the Reply Declaration of Vernon M. Winters and Exhibit 1 attached to said declaration. (D.I. 64).

3. In his declaration, Mr. Winters discussed information from the deposition of Sandoz employee Dr. Rüdiger Jankowsky, Global Program Leader, Biopharmaceuticals, as well as attaching transcript excerpts as Exhibit 1 to his declaration. Defendants' deposed Dr. Jankowsky on Friday, September 13, 2013, and Sandoz designated the deposition transcript as Highly Confidential.

4. The information summarized below is commercially sensitive and trade-secret information that Sandoz maintains confidentially and does not make publicly available. Disclosure of this information would provide Sandoz's potential or actual competitors with access to the precise sums of money that Sandoz has expended on the development of its etanercept product, details concerning Sandoz's research and development, production, and launch of its product, and its strategic decision making with regard to product development. If this confidential information were made public, Sandoz would suffer competitive harm. Sandoz designated this information as confidential in order to prevent its disclosure to competitors.

5. With regard to the Reply Declaration of Vernon M. Winters, the following sections from his declaration should be filed under seal:

- a. Paragraph 2 (A), (E), and (F), which discuss the dollar amount of Sandoz's investment in the development of its biosimilar product;
  - b. Paragraph 2 (G) and (Y), which discuss Sandoz's confidential plans for the timing of the development of its biosimilar product;
  - c. Paragraph 2 (N) and (O), which discuss confidential communications between Sandoz and the FDA;
  - d. Paragraph 2 (Z), and (AA), which discuss Sandoz's strategic business decisions and planning for its biosimilar product.
- (D.I. 67 at 1-3). As **Exhibit A** to my declaration, I have attached a proposed redacted version of Mr. Winters' declaration, redacting the information identified above.

6. Exhibit 1 to the Reply Declaration of Vernon M. Winters are excerpts from Dr. Jankowsky's deposition containing confidential information about Sandoz's development of, and strategic and commercial plans for, its biosimilar etanercept product. Specifically, the following should be filed under seal:

- a. Ex. 1A at 10:25-11:8, 11:13-25; Ex. 1E and 1F at 23:12-26:6; Ex. 1E, 1F and 1G at 26:17-30:25; Ex. 1H at 33:18-25; and Ex. 1I at 34:4-11, which disclose confidential information regarding the timing of Sandoz's expenditures, the purpose of Sandoz's expenditures, and the dollar amount of Sandoz's expenditures for its biosimilar product;
- b. Ex. 1C and 1D at 20:11-25; Ex. 1K and 1L at 36:21-13, 37:19-21; Ex. 1M at 39: 7-10; and Ex. 1Q 48:1-22, which disclose confidential information regarding the timing of Sandoz's clinical trials, the details of Sandoz's clinical trials, and factors affecting Sandoz's decision whether or not to pursue those clinical trials;
- c. Ex. 1D at 21:18-25; Ex. 1E at 22:17-23:11; Ex. 1V at 54:6-10; and Ex. 1Y and 1AA at 91:7-12, which disclose confidential information regarding Sandoz's biosimilar product such as descriptions of the product and details regarding its production;
- d. Ex. 1E at 26:7-16; Ex. 1I and 1J at 34:12-35-6; Ex. 1Y, YAA, and YBB at 91:24-93:7; and Ex. 1Z at 56:6-57-6, which disclose confidential information regarding Sandoz's commercial plans for launching and selling its biosimilar product; and
- e. Ex. 1M at 39:12-25; Ex. 1N at 1O at 41:2-25, which disclose confidential communications between Sandoz and the FDA regarding Sandoz's biosimilar product.

(D.I. 67-1). As **Exhibit B** to my declaration, I have attached a proposed redacted version of Exhibit 1 to Mr. Winters' declaration, redacting the information identified above.

1 I declare under penalty of perjury that the foregoing is true and correct.

2  
3 Dated: November 5, 2013

4  
5 /s/ Brian Hirsch  
6 Brian Hirsch

7 **FILER'S ATTESTATION**

8 I, James M. Hilmert, am the ECF user whose identification and password are being used to  
9 file this declaration. In accordance with Local Rule 5-1(i)(3), I hereby attest that the above-named  
10 signatory concurs in this filing.

11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
Winston & Strawn LLP  
101 California Street  
San Francisco, CA 94111-5802